

REMARKS

This Amendment is submitted in reply to the non-final Office Action mailed on September 20, 2007. No fee is due in connection with this Amendment. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 119108-3 on the account statement.

Applicants do not acquiesce in the correctness of the rejections or objections and reserve the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further Applicants reserve the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

Claims 22-28, 30-37 and 42-43 are currently pending. Claims 1-18 were previously canceled. Claims 19-21, 29, 38-41 and 44-51 were previously withdrawn. In the Office Action, Claim 27 is objected to; Claims 24, 30 and 32-37 are rejected under 35 U.S.C. §112, second paragraph; Claims 22-28, 30-37 and 42-43 are rejected under 35 U.S.C. §102; and Claims 22-28, 30-37 and 42-43 are rejected under 35 U.S.C. §103. In response Claims 22, 24, 30 and 32 have been amended, and Claims 31, 34 and 42-43 have been canceled. These amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

Applicants submit herewith an Information Disclosure Statement including copies of the documents cited therein.

In the Office Action, Claim 27 is objected to as failing to further limit the subject matter of a previous claim. Applicants respectfully disagree. Claim 27 is directed to specific types of gum that further limit the gum recited in Claim 26. That the gum of Claim 26 is part of a Markush group does not change this. Claim 27 still limits the type of gum of Claim 26. There is nothing in the MPEP to prevent a dependent claim from further limiting or defining one or more members of a Markush group. Accordingly, Applicants respectfully submit that the objection to Claim 27 be withdrawn.

In the Office Action, Claims 30 and 32-37 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim

the subject matter which Applicants regard as the invention. Specifically, the Patent Office alleges that the term "non-viscous" in Claim 30 is a relative term rendering the claim indefinite. In response, Claim 30 has been amended include the elements of Claim 31. Claim 30 recites, in part, that the composition has a viscosity of less than about 500 mPa·s at room temperature. Based on at least these noted reasons, Applicants believe that Claims 30 and 32-37 fully comply with 35 U.S.C. §112, second paragraph.

In the Office Action, Claims 24 and 32 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Patent Office alleges that the ratios without units render the claims indefinite. In response, Claims 24 and 32 have been amended to recite the units of the ratios. The amendment is supported in the specification, for example, at page 10, lines 10-13. Based on at least these noted reasons, Applicants believe that Claims 24 and 32 fully comply with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejections of Claims 24, 30 and 32-37 under 35 U.S.C. §112 be withdrawn.

In the Office Action, Claims 22, 26-28, 30, 34-37 and 42-43 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,210,686 to Bell ("*Bell*"). Claims 22-23, 26-28, 30-31, 34-37 and 42-43 are rejected under 35 U.S.C. §102(b) as anticipated by AU 9873118A to Jaussan ("*Jaussan*"). Claims 22, 25-27, 30, 33-36 and 42 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,589,511 to Shimizu ("*Shimizu*"). Claims 22, 25-27, 30, 33-36 and 42 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,470,839 to Laughlin ("*Laughlin*"). Claims 22-28 and 30-37 are rejected under 35 U.S.C. §102(b) as anticipated by EP 0323510 to Ohta ("*Ohta*"). Claims 22, 26-28, 30, 34-37 and 42-43 are rejected under 35 U.S.C. §102(b) as anticipated by GB 2021948A to Heath ("*Heath*"). Applicants respectfully disagree with and traverse these rejections for at least the reasons set forth below.

Applicants have amended independent Claims 22 and 30 to recite, in part, a composition for oral or enteral administration comprising a moderately hydrolyzed protein selected from the group consisting of wheat protein, egg protein, collagen, whey protein, casein, soy protein, pea protein, muscle protein, gluten, fibrillar protein, silk protein and combinations thereof. The amendment as discussed above is fully supported in the specification, for example, on page 3,

line 32 to page 4, line 14 and page 7, line 20 to page 8, line 4. For example, the specification explicitly teaches that the term "moderately hydrolyzed protein" refers to protein that has a molecular weight between about 1 and about 20 kDa. In contrast, Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

A potential difficulty in adopting viscous soluble fiber in a composition concerns the type of viscosity that is generally associated with levels considered to be therapeutic in the treatment of certain diseases such as diabetes or metabolic syndrome. In particular, the high viscosity of fiber compositions may render problematic the preparation of the fiber composition for oral and enteral administration, especially for patients requiring tube-feeding. Applicants have surprisingly found that the fiber compositions of the present claims have advantageous characteristics in that the viscosity of the fiber compositions may be modulated, for example, reversed, delayed, and/or re-increased. In accordance with embodiments of the present claims, a modulated viscosity refers to a viscosity of a soluble viscous fiber composition that has been modulated (e.g. lowered or totally/partially re-increased) by moderately or extensively hydrolyzing the viscosity-lowering protein. As a result, the fiber compositions of the present claims can provide, in part, a sufficiently low viscosity to be enterally and/or orally administered.

Bell, Jaussan, Shimizu, Laughlin, Ohta and Heath fail to disclose or suggest a composition for oral or enteral administration comprising a moderately hydrolyzed protein selected from the group consisting of wheat protein, egg protein, collagen, whey protein, casein, soy protein, pea protein, muscle protein, gluten, fibrillar protein, silk protein and combinations thereof as required, in part, by Claims 22 and 30. In fact, *Bell, Jaussan, Shimizu, Laughlin, Ohta and Heath* fail to even recognize the advantages, benefits and/or properties of a fiber composition for oral or enteral administration comprising a moderately hydrolyzed protein and having modulated viscosity properties in accordance with the present claims. For at least the reasons discussed above, Applicants respectfully submit that Claims 22 and 30 and the claims that depend from Claims 22 and 30 are novel, nonobvious and distinguishable from the cited references.

Accordingly, Applicants respectfully request that the rejections of Claims 22-28, 30-37 and 42-43 under 35 U.S.C. §102 be withdrawn.

In the Office Action, Claims 22-28, 30-37 and 42-43 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,287,623 to Nakayama ("*Nakayama*").

Applicants believe this rejection is improper and respectfully traverse it for at least the reasons set forth below.

Nakayama fails to disclose or suggest a composition for oral or enteral administration comprising a moderately hydrolyzed protein selected from the group consisting of wheat protein, egg protein, collagen, whey protein, casein, soy protein, pea protein, muscle protein, gluten, fibrillar protein, silk protein and combinations thereof as required by Claims 22 and 30. For at least the reasons discussed above, *Nakayama* does not teach, suggest, or even disclose all of the elements of the present claims, and thus, fails to render the claimed subject matter obvious.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 22-28, 30-37 and 42-43 be reconsidered and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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